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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,972	03/07/2005	Axel Brattstrom	26638U	7955
20529	7590	02/28/2006	EXAMINER	
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			CLARK, AMY LYNN	
			ART UNIT	PAPER NUMBER
			1655	
DATE MAILED: 02/28/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,972	<b>Applicant(s)</b> BRATTSTROM, AXEL	
	<b>Examiner</b> Amy L. Clark	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03/07/2005</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Specification***

The abstract of the disclosure is objected to because the number of words in the abstract exceeds the limit of 150. Correction is required. See MPEP § 608.01(b).

### ***Claim Objections***

Claim 1, lines 12 and 13 are objected to because of the following informalities: In line 12, "Wherein" should be replaced with wherein and in line 13, a the word or is missing in the sentence. Insert "or" between "acceptable" and "an". Appropriate correction is required.

Claim 2, line 3 is objected to because of the following informalities: the phrase "a C<sub>1-4</sub> alcanol or a mixture or such alcanol with water" is grammatically incorrect ("or such alcanol" should read "of said alcanol") and the word "alcanol" is not a recognized word in the English language. Appropriate correction is required.

Claim 6, line 2 is objected to because of the following informalities: the phrase "by extracting of *Cimicifuga racemosa*" is grammatically incorrect. The phrase should read, "by extraction of *Cimicifuga racemosa*" or "by extracting *Cimicifuga racemosa*". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7 and 8 provide for the use of an extract, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7 and 8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 2 are rendered uncertain by the phrase "The method of Claim 1, wherein said extraction agent is a polar substance and preferably said extraction agent is a polar substance and preferably a C<sub>1-4</sub> alkanol or a mixture or such alkanol with water". It is unclear as to what applicant means by "a C<sub>1-4</sub> alkanol or a

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mixture or such alcanol with water". The term "alcanol" is not a recognized word in the English language and the phrase "or such alcanol with water" is unclear. The term "alcanol" appears to be a spelling error and the word is taken by The Office to be "alcohol". The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

The metes and bounds of Claim 4 are rendered uncertain by the phrase "at least about 100 Dalton units" because the simultaneous recitation of the terms "at least" and "about" makes the claim language inconsistent. The lack of clarity renders the claims indefinite since the resulting claims do not clearly set forth the metes and bounds of the patent protection desired.

Claim 9, line 5, recites the abbreviation "PVP". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreuter et al. (A).

Kreuter teaches a process for producing an extract of *Cimicifuga racemosa* (See column 10, claim 15) comprising of mixing *Cimicifuga racemosa* charged in a fresh or dried state with at least one solvent, which can be a polar solvent, such as water, C<sub>1</sub> to C<sub>4</sub> alcohols (such as ethanol, glycerol or propylene glycol or mixtures of water and alcohol, See column 11, claims 17-20) and at least one agent, such as polyvinylpyrrolidone (PVP), polyethylene glycol or polypropylene glycol (See column 11, claims 26 and 27), with a molecular weight ranging from 4,000 to 35,000 (See column 9, claim 4), which reads on an organic polymer capable of being dispersible or soluble in an extraction agent with a an average molecular mass of at least about 1000 Dalton units, extracting the plant or plant parts with the solvent, filtering the insoluble compounds to obtain a filtrate, concentration the filtrate to a spissum or to a dry extract (See column 9, claim 1), which reads on at least partial removal of said extraction agent. Kreuter further teaches an extract of *Cimicifuga racemosa* containing pharmaceutically acceptable administrative forms (See paragraph 3, lines 31-35).

Therefore, the reference anticipates the claimed subject matter.

Claims 9 is rejected under 35 U.S.C. 102(a) as being anticipated by Houston et al. (B).

Houston teaches a pharmaceutical composition (which reads on medicament) comprising of an extract of black cohosh (See page 3, paragraph 0031), which is synonymous with *Cimicifuga racemosa*, and polyvinylpyrrolidone (See page 7, paragraph 0083). Houston further teaches that black cohosh contains isoflavones, which are used to treat hot flashes in post-menopausal women (See page 1, paragraph

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0009, continued onto page 2). Houston does not expressly teach that the composition is capable of being used as a substitute for or a compliment to hormone replacement therapy, however the composition as taught by Houston is one in the same as that claimed by Applicant, therefore, the properties of the composition (as a substitute for or a compliment to hormone replacement therapy), as claimed by Applicant, are inherent to the composition taught by Houston. It is also important to note that product-by-process claims are not patentably distinct from product claims (See MPEP § 2111.01).

Therefore, the reference anticipates the claimed subject matter.

\* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy L. Clark  
AU 1655

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February 6, 2006

*Michele P. Flood*  
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